



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/632,008

07/31/2003

Robert E. Richard

02-263

9358

27774 7590 12/13/2010
MAYER & WILLIAMS PC
251 NORTH AVENUE WEST
Suite 201
WESTFIELD, NJ 07090

EXAMINER

ALAWADI, SARAH

ART UNIT

PAPER NUMBER

1619

MAIL DATE

DELIVERY MODE

12/13/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/632,008 | Applicant(s) RICHARD ET AL. | |
| | Examiner SARAH AL-AWADI | Art Unit 1619 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/19/2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-9,11-16,18-20,22,23 and 28-37 is/are pending in the application.
- 4a) Of the above claim(s) 13,30,33,34 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-9,11-12, 14-16,18-20,22,23 and 28-29, 31-21, and 35-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Applicants arguments/remarks filed on 10/19/2010 is acknowledged.

Claims 1, 5-9, 11-12, 14-16, 18-20, 22-23, 28-29, 31-32

WITHDRAWN CLAIMS

Since applicant has received an action on the merits for the originally presented invention, which includes the supplemental polymer, this invention has been constructively elected by original presentation for prosecution on the merits. Election becomes fixed when the claims in an application have received an action on their merits by the Office. The general policy of the Office is not to permit the applicant to shift to claiming another invention after an election is once made and action given on the elected subject matter. Note that the applicant cannot, as a matter of right, file a request for continued examination (RCE) to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined (i.e., applicant cannot switch inventions by way of an RCE as a matter of right). When claims are presented which the examiner holds are drawn to an invention other than the one elected, he or she should treat the claims as outlined in MPEP § 821.03.

In the instant case, claims 33, 34 and 37 are withdrawn from further consideration as being directed towards a non-elected invention. Applicants have elected supplemental polymers to include styrene-isobutylene copolymers in the response received on 05/12/1010 and the claims were examined including the supplemental polymer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 6-9,11-12, 14-16,18-20, 22-23, 28-29, and 31-32 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk, United States Patent 6,545,097, Smith et al., United States Patent, 5,639,810, and Hamilton et al., United States Patent, 6,896,842

Art Unit: 1619

Pinchuk et al. teach a composition for delivering therapeutic agents such as paclitaxel, see column 7, line 7 and abstract. The composition comprises a block copolymer made up of an elastomeric block and a thermoplastic block, and is used to coat at least a portion of an intravascular or intervacular medical device such as stent, see abstract and column 2, line 34. The thermoplastic polymers (high Tg block) may be used as end blocks, see column 3, lines 44-57. The elastomeric blocks can include the broad genus of polyolefin blocks. The thermoplastic blocks can include vinyl aromatic polymer blocks such as blocks of styrene (elevated Tg non siloxane unit), see column 1 lines 62-67- column 2 lines 1-3. The thermoplastic blocks (elevated Tg blocks) can comprise a mixture of two different types of Tg non siloxane units including styrene, methylstyrene, acrylate blocks, vinyl aromatic blocks or mixtures thereof, see column 1, lines 62-38-column 2, lines 1-3. Pinchuk et al. teach that blends of polymers including polystyrene-polyisobutylene-polystyrene copolymers can be added with the block copolymers with the advantage of increasing the strength of the coating see column 17, lines 29-38. The block copolymers of Pinchuk et al. can include grafting as Pinchuk et al. teach star-shaped configurations of the block copolymers, see column 3, lines 62-64. The star shaped configurations may be in B(AB)_n or A(BA)_n triblock configurations wherein B is the thermoplastic block and n=3 or more thus forming the star configuration (graft), see column 3, lines 50-57. Pinchuk et al. teach the use of barrier layers which coat the copolymers of the invention in order to retard diffusion of the therapeutic agent and prevent a burst phenomenon, see column 16, lines 54-67. Pinchuk et al. teach the use of elastomeric and thermoplastic blocks, see column 1, lines 54-55.

Art Unit: 1619

Pinchuk et al. does not expressly teach wherein the elastomeric block comprises dimethylpolysiloxane.

Smith et al. teach thermoplastic block copolymers having methylstyrene end blocks and polydimethylsiloxane (elastomeric) intermediate blocks. Smith teach that the elastomeric materials are useful for medical and therapeutic device applications, see abstract.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate the elastomeric blocks of polydimethylsiloxane with the thermoplastic blocks taught by Pinchuk et al. One would have been motivated to do so because it is taught by Smith et al. that such block copolymers are said to contain good strength and resistance to tearing, see column 5, lines 3-4. There would have been a reasonable expectation of success because Pinchuk et al. teach combining thermoplastic blocks including methylstyrene or styrene with elastomeric blocks. Furthermore, both references disclose using block copolymers for medical device applications. Regarding the elongation of break of at least 25% at ambient temperature, and the rubbery and hard phases of the polymers, these are considered a property of the block copolymer claimed. As the combined teachings of Pinchuk and Smith teach the structural block copolymer (elastomeric and thermoplastic blocks) it is expected that the block copolymer exhibits the same properties as the claimed invention. Furthermore MPEP 2112.01 recites if the composition is physically the same, it must have the same properties.

Neither Pinchuk nor Smith disclose sterilization of the device by radiation, however sterilization is an inherent property to any medical device which are inserted into the body. Furthermore, as disclosed by Hamilton et al. thermoplastic elastomers for medical devices are resistant to radiation, thus enable them to be sterilized by radiation, see column 3, lines 54-62.

RESPONSE TO REMARKS

Applicants argue that the materials described in Smith which incorporates Kaebler by reference are directed towards sealing materials. Sealing materials, while useful for many medical applications are clearly inappropriate for forming polymeric carrier regions like those claimed which comprise a therapeutic agent and which release the therapeutic agent upon administration to a patient, thus the art teaches away.

In response, the Examiner respectfully submits that Smith et al. teach that the elastomer compositions disclosed are for use in medical and therapeutic device applications, see abstract. While Smith et al. does not expressly disclose a stent, it would have been within the purview of one of ordinary skill in the art to arrive at the instant invention through the teachings of Pinchuk and Smith because Smith teaches that the elastomer block polymers disclosed are useful for therapeutic and medical devices. Furthermore, Smith expressly teaches that such block copolymers contain good strength and resistance to tearing, see column 5, lines 3-4. Therefore one would have been motivated to use the polymers disclosed in Smith which already teaches medical device applications, with the medical devices of Pinchuck as they provide good strength and resistance to tearing and are capable of being used with medical device applications. One would expect that polymeric carrier regions which contain a therapeutic agent would need to impart good strength and resistance to tearing on medical devices so that the drugs do not get released prematurely. Therefore, the Examiner respectfully submits that the polymers disclosed in Smith et al. for medical device applications are necessarily capable of being applied as carriers for medical devices.

NEW Claim Objections

Claim 35 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, claim 35 is a duplicate of claim 29.

CONCLUSION

Applicant's arguments/remarks are considered unpersuasive. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah Al-Awadi whose telephone number is (571) 270-7678. The examiner can normally be reached on 9:30 am - 6:00 pm; M-F (EST).

Art Unit: 1619

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bonnie Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARAH AL-AWADI/
Examiner, Art Unit 1619

/Shanon A. Foley/
Primary Examiner, Art Unit 1619